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A Coaching Program to Improve Dietary Intake of Patients with CKD: ENTICE-CKD

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Abstract

Background: The dietary self-management of chronic kidney disease (CKD) is challenging. Telehealth interventions may provide an effective delivery method to facilitate sustained dietary change.

Methods: This pilot randomized controlled trial evaluated secondary and exploratory outcomes following a dietitian-led telehealth coaching intervention to improve diet quality in people with stage 3-4 CKD. The intervention group received phone calls every 2 weeks for 3 months (with concurrent tailored text messages for 3 months), followed by 3 months of tailored text-messaged without telephone coaching, to encourage a diet consistent with CKD guidelines. The control group received usual care for 3 months followed by non-tailored educational text messages for 3 months.

Results: Eighty participants (64% male), aged 62±12 years were randomized to the intervention or control group. Telehealth coaching was safe, with no adverse events or changes to serum biochemistry at any time point. At 3 months, the telehealth intervention, compared with the control, had no detectable effect on overall diet quality on the Alternative Health Eating Index (+3.2 points, 95% confidence interval [CI] -1.3 to +7.7), nor at 6 months +0.5 (95% CI -4.6, +5.5). There was no change in clinic blood pressure at any time point in any group. There were significant improvements in several exploratory diet and clinical outcomes, including core food group consumption, vegetable serves, fiber intake and body weight.

Conclusions: Telehealth coaching was safe, but appeared to have no effect on the Alternative Healthy Eating Index or clinic blood pressure. There were clinically significant changes in several exploratory diet and clinical outcomes which require further investigation.

Keywords: Chronic kidney disease, diet, dietary pattern, mobile health, self-efficacy, smartphone, telehealth, telemedicine, text messaging, trial, weight loss

Introduction

Dietary modification is a key management strategy in CKD to treat electrolyte abnormalities and potentially prevent CKD progression and cardiovascular events.[1,2] It is also considered to be a top research priority by clinicians, patients and caregivers.[3] However, patients frequently experience dietary management as overwhelming, difficult to follow, and report contradictory messages that thwart implementation.[4]

The majority of dietary interventions for pre-dialysis CKD patients are delivered in one-off dietary education sessions, without ongoing follow up.[5] Telephone coaching is a basic form of telehealth shown to be effective at promoting adherence to complex dietary recommendations in chronic disease.[6] Telephone coaching in combination with one-on-one support can reduce dietary sodium intake[7] and increase knowledge of self-management behavior in people with CKD.[8] M-Health, also falls under the definition of telehealth, but extends more broadly to the use of mobile phones for healthcare delivery, is perceived as flexible and cost-effective[9] and has improved diet quality in people with coronary heart disease.[10] While there has been no telehealth intervention demonstrated to effectively support diet quality improvements in CKD, recent patient engagement studies suggest that people with CKD are open to using telephone and m-health methods for their dietary self-management.[11,12] However, it is uncertain whether telehealth coaching interventions can improve diet quality in people with stage 3-4 CKD.

A pilot randomized controlled trial (ENTICE-CKD study) recently demonstrated the feasibility and acceptability of a telehealth-delivered intervention to improve dietary self-management.[13] Eighty participants were randomized to the intervention and control group, with 4% attrition and 96% of all coaching calls completed to protocol. All participants in the intervention arm (100%) believed the tailored text messages were useful in supporting their dietary self-management. Sixty-nine percent of participants in the control group felt that the non-tailored

text messages were useful in supporting diet change. Participants viewed the intervention as an acceptable, personalized alternative to face-face clinic consultations, and were satisfied with the frequency of contact.[13] This current study aims to evaluate the secondary and exploratory outcomes ENTICE-CKD telehealth coaching intervention to improve diet quality in people with stage 3-4 CKD.

Methods

Study design

The Evaluation of iNdividualized Telehealth Intensive Coaching to promote healthy Eating and lifestyle in Chronic Kidney Disease (ENTICE-CKD) study was a 6-month parallel-group, randomized-controlled trial conducted across three tertiary hospitals in Australia (November 2016 to November 2017). This study was designed as a pilot trial to primarily test the feasibility and acceptability of the telehealth program to improve diet quality.[13] This work reports on the diet-related outcomes and exploratory clinical outcomes listed in the clinical trial registration (ACTRN12616001212448). Ethics was approved by the Metro South Human Research Ethics Committee.

Participants

A detailed description of participant selection, screening and intervention materials are described elsewhere.[13] Any participant aged over 18 years with stage 3-4 CKD (eGFR 15-59 ml/min/1.73m^2 calculated using the CKD-EPI formula),[14] with access to a mobile phone and ability to provide written informed consent, were eligible to participate. People on dialysis, non-English speaking, or deemed unsafe to participate, were excluded.

Randomization and allocation concealment

The randomization schedule was created in RedCap[15] and participants were allocated on a 1:1 ratio, stratified by recruitment site and diabetes status using a computer-generated random number list. Allocation was concealed from the site investigators. An offsite trial coordinator randomized participant and notified the intervention coach (who had never met the participant and did not work in the same hospital), who in turn notified participants of their allocation.

Intervention

All specific details relating to the intervention are reported according to the template for intervention description and replication (TIDieR) items (1-10),[16] detailed in Table 1. Details about intervention fidelity (TIDieR items 11 and 12) are published elsewhere.[13] Briefly, following a face-to-face baseline assessment with the local site investigator, all participants received the ENTICE-CKD workbook (main content summarized in Table 1), which was designed by dietitians specialized in kidney disease, with extensive academic, clinician, and consumer input. Participants randomized to the intervention group completed the telehealth intervention in two phases. The first phase involved individualized, telephone-based coaching from a dietitian (referred to as coaches) every 2 weeks for 3 months (6 calls total), with weekly tailored text messages (detailed in Table 1) delivered within a set protocol at a frequency determined by the participant. Phase 2 of the intervention involved no further telephone coaching calls, however participants continued to receive the same tailored text messages as phase 1 at a different frequency (Table 1).

Control group

Participants allocated to the control group received two phases of care. In phase 1 (months 0-3), they received the same ENTICE-CKD workbook as the intervention group and continued to receive usual care, but no other intervention. After 3 months, participants commenced phase

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2 (months 3-6), a delayed contact intervention, including non-tailored text-messages in which participants could choose the text frequency. The content of the text messages was based on improving dietary quality as per the Australian Dietary Guidelines[17] and the Kidney Health Australia Caring for Australasians with a Renal Impairment guidelines.[18] Although these text messages are not considered 'usual care', they were utilized as a retention mechanism, and to generate hypotheses around the potential benefit of tailored text-messages compared to non-tailored text messages to improve dietary intake in CKD.

Outcome assessment

The primary outcome of the trial was feasibility and acceptability which have been previously reported..[13] In this study, we report all secondary and exploratory outcomes of ENTICE-CKD. Data were collected at baseline, 3 months and 6 months. Participants' study visits were scheduled hours apart to mitigate contamination bias. To maintain blinding of allocation for site investigators, participants were asked not to disclose which group they had been assigned to during their study visits. Site investigators performed all objective clinical measures, whereas serum and urine pathology were perfomed as part of usual care (using random samples) by local NATA-accredited laboratories. Self-reported surveys and health care utilization were completed by participants at all times, either on site, returned via registered post, or completed via an online email link.

Secondary outcomes

Overall change in diet quality was measured by the Alternative Healthy Eating Index - 2010, which assesses adherence to dietary guidelines.[19] The Australian Eating Survey[20] was used to capture and measure all diet outcome measures, including eight of the ten Alternative Healthy Eating Index food scoring components, except for trans-fat and n-3 polyunsaturated fatty acids, which were calculated using FoodWorks (version 18). All ten food scoring components of the

Alternative Healthy Eating Index were summed to generate an Alternative Healthy Eating Index score ranging from 0 to 110 (higher score reflecting higher adherence).[19]

Change in clinic blood pressure was measured with a calibrated digital blood pressure monitor in accordance with the recommended protocol from the American Heart Association.[21]

All serum investigations were performed at local NATA-accredited laboratories and used to assess changes in potassium, bicarbonate and phosphate for safety monitoring.

Exploratory outcomes

Data collection methods for the exploratory measures of diet quality, nutrient intake, antihypertensive medication requirements, body weight, waist circumference, estimated glomerular filtration rate (eGFR), albuminuria, Assessment of Quality of Life' questionnaire (AQoL-4D),[22] and economic evaluation (program costs, participart food costs and healthcare expenditure) are reported in Supplemental Table 1.

Safety monitoring

Participants were trained to identify symptoms of hypotensive episodes between study visits, defined as systolic blood pressure <100 mmHg or diastolic blood pressure <60 mmHg. Assigned coaches monitored symptoms and/or large changes in potassium (increase in potassium intake >50mmol/day) or sodium intake during each coaching call.[23,24] If concerns were identified, participants were advised to see their general practitioner.

Statistical analysis

The study was designed as a pilot study.[25] A sample size of 30-40 participants per study arm was determined so as to reliably interpret data to inform power calculations for future intervention studies.[26] A one-way analysis of covariance was conducted to assess the main effects of the categorical independent variable (tailored telephone-coaching and text-messages versus control (phase 1); or tailored text-messages versus non-tailored education-only text

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messages (phase 2)) on a single continuous dependent variable, after controlling for the effects of the baseline covariate. Categorical outcomes were assessed by the standard chi-square test. Given the small amount of missing data across the sample (<10%), all analyses were performed using an available case analysis. As a form of sensitivity analysis, we also performed intention to treat using the last-value carried forward technique. Both this and the available case analyses reported the same overall statistical (and point-estimate) significance (data available on request). There were no further subgroup or additional analyses completed. Statistical analyses were performed using SPSS Statistics for Windows (version 22.0. Chicago: SPSS Inc.), with a 2-sided p value (≤ 0.05) considered statistically significant. The economic evaluation was conducted using the mean costs and the health outcomes of 1) QALYs gained over 3 months, and 2) the proportion of participants achieving a 5-point improvement in diet quality over 3 months. Incremental cost effectiveness ratios (ICERs) were calculated as the incremental cost per QALY gained, and the incremental cost per additional patient achieving a meaningful improvement in diet quality, using the following formula.

$$ICER = \frac{(Total\ Cost_{Intervention} - Total\ Cost_{Control})}{(Total\ Outcomes_{Intervention} - Total\ Outcomes_{Control})}$$

All cost-effectiveness analyses were performed using Microsoft Excel (Microsoft Corporation, Redmond, Washington, DC, US).

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Results

Eighty participants were randomized and 76 completed the 6-month study (Figure 1). Except for servings of vegetables per day, where intervention participants had a 1.2 serve lower intake at baseline, all other baseline characteristics were not statistically different between groups (Table 2). However, there was evident clinical differences between the groups which may be meaningful in practice. Mean age of the intervention group was 63±12 years compared to 61 years in the control arm, the intervention arm also had a higher proportion of Asian, Caucasian and Indigenous ethnicities, whereas the control arm had a higher proportion of European and other ethnicities. Intervention participants had a 5.8kg higher weight, and a 5.9cm higher waist circumference compared to control participants which are important clinical characteristics to note. Participants had a high diet quality at baseline, with overall mean Alternative Healthy Eating Index values of 71.4 and 69.6 points for the intervention and control groups, respectively.

Change in dietary intake

Compared to controls, telehealth coaching did not significantly change Alternative Healthy Eating Index at 3 or 6 months. However, individual measures of diet quality were significantly changed following the telehealth intervention, including an increase in energy intake from the core food groups at 3 months (5.8%, 95% CI 0.9 to 10.7) and 6 months (5.4%, 95% CI 1.0 to 9.8), increased vegetable intake at 3 months by 1.5 serves/day (95% CI 0.6 to 2.3) and increased grams of dietary fiber by 6.1 g/day (95% CI 3.2 to 8.9). These improvements were not sustained at 6 months (Table 3).

Blood pressure and serum electrolytes

There was no change in blood pressure or serum electrolytes in either group at any time point. There were no incidences of hypotensive episodes or any other adverse events (including hyperkalemia).

Body mass

Telehealth coaching participants had a greater decrease in body weight at 3 months (-1.9 kg, 95% CI -3.3 to -0.4) compared to control group participants, which slightly attenuated at 6 months (-1.5 kg. 95% CI -3.5 to +0.4) (Supplemental Table 2). The intervention appeared to make little difference to waist circumference at both time points (Supplemental Table 2).

Clinical parameters

The total number of antihypertensive medications use at 3 months in the intervention and control groups respectively increased in 1 (3%) and 9 (24%) of participants and decreased in 5 (13%) and 2 (5%) of participants (φ=0.3; p=0.017, Supplemental Table 2). No difference in anti-hypertensive medication use was observed at 6 months (p=0.1, Supplemental Table 2).

Quality of life

Telehealth coaching appeared to result in no significant difference to AQoL-4D (Table 3) or QLAYS gained (Supplemental Table 2) between groups at both 3 and 6 months.

Cost effectiveness

Over the 6-month trial period, the intervention cost AUD 297.76 (USD 204.01) compared to AUD 42.93 (USD 29.41) in the control group; total costs per participant were AUD 1,780.88 (USD 1,220.20) for the intervention group and AUD 1,789.74 (USD 1,226.15) for the control group (Supplemental Table 3). At 3-months, the intervention was both less costly and more effective (dominant) than the control group in terms of both the proportion of patients achieving a meaningful change in diet quality, and in QALYs gained.

Adverse events

There were no adverse events or unintended consequences to any participant in any group throughout the study.

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Discussion

This paper aimed to evaluate the secondary and exploratory outcomes of the ENTICE-CKD telehealth coaching intervention to improve diet quality in people with stage 3-4 CKD. The intervention was established to be safe, but did not lead to result in a significant improvement in the secondary outcome of diet quality, as measured by the Alternative Healthy Eating Index, or clinic blood pressure at any time point. There were a number of exploratory dietary outcomes which did significantly improve following intensive telehealth coaching, including energy intake from the core food groups and vegetables and dietary fiber intake, compared to controls at 3 months. It is important to not overstate the intervention effects observed as a large number of secondary and exploratory outcomes were examined in this pilot study with a small number showing statistically significant effects (some of which could be by chance), and notably, the majority of these effects were not sustained at the 6-month conclusion of the study. As the examination of dietary outcomes was a secondary aim of the ENTICE-CKD study, it was underpowered to detect meaningful change in these outcomes. However, these observed effects in diet and clinical outcomes highlight the potential to examine this further in larger, adequately powered clinical trials.

Although the intervention group improved their overall diet quality compared to their baseline intake, there was no statistically significant difference in comparison to the control group at any time-point. Whilst noting that the study was underpowered, it is interesting that the mean intervention effect at 3 months equated to an improvement in Alternative Healthy Eating Index score of approximately ¼ standard deviation (SD) in favor of the intervention group, with the 95% confidence intervals encompassing effects in the order of up to half a standard deviation improvement. Whilst not statistically significant effect, the observed within-group changes in intervention participants' Alternative Healthy Eating Index scores are consistent with the minimal clinically important changes suggested to translate to reduced risk of morbidity and

mortality.[27] It is also plausible that participants' high diet quality at baseline (in both study groups) resulted in ceiling effects, limiting the magnitude of improvement possible through further dietary intervention. In fact, both study groups at a baseline had a mean Alternative Healthy Eating Index score that would be in the highest quintile in observational studies, which have demonstrated kidney and cardiovascular benefit with diet quality.[19,28]

Improving vegetable and fiber intake are important characteristics of diet quality.[29] In our study, medium to large (d >0.5) statistically significant effects were observed for these exploratory outcomes. In an Australian cohort study, consuming more vegetables and fruit was shown to be associated with a 65% lower risk of death over a 4-year follow-up in stage 3-4 CKD.[30] In the only available randomized trial, people with stage 4 CKD randomized to an intervention targeting higher vegetable and fruit intakes, had lower rates of metabolic acidosis, and greater reductions in blood pressure and body weight compared to a standard sodium bicarbonate prescription over a 5-year follow up period.[32] Intervention group participants significantly increased their consumption of dietary fiber by over 6g per day at 3 months to exceed the 30g per day as recommended in current guidelines.[33] Meta-analysis in CKD populations has shown that dietary fiber consumption of approximately 27g/day can significantly reduce serum urea and creatinine levels.[34] Long-term exposure to a diet higher in fiber may also reduce inflammation and mortality risk.[35]

Blood pressure is a controllable risk factor for CKD progression, but was unchanged throughout the study. Intervention participants did reduce their overall antihypertensive medication pill burden at 3-months, which may reflect a possible benefit of improving blood pressure control in CKD. For example, the efficacy of some antihypertensive medications (notably Angiotensin-Converting-Enzyme inhibitors and Angiotensin Receptor Blockers) are enhanced with effective sodium restriction.[37,38] As sodium reduction was observed in both study groups, the reduction in antihypertensive medication prescriptions in the intervention

group may have attenuated a potential change in blood pressure which we could attribute to the intervention itself. However, antihypertensive medication burden was only an exploratory outcome and therefore this is not conclusive.

Excessive weight gain carries a higher burden of cardiovascular risk and CKD progression.[39] While weight change was an exploratory outcome and not a focus of the intervention, the magnitude of change (-1.9kg) was similar to that of two recent diet and physical activity randomized trials, in which both studies demonstrated a weight loss of 1.8kg in 4 month and 12 month interventions.[40,41] Although the intervention effect on weight was statistically significant, this magnitude of weight loss is unlikely to be associated with clinical benefit, with weight losses of at least 5% of body weight associated with improvements in health outcomes.[44]

The tailored telehealth program (phone coaching plus text-messages) was both less costly and more effective at 3 months for improving diet quality compared to the control group. We were unable to analyze the 6-month cost-effectiveness of the ENTICE-CKD program, as the tailored telehealth intervention was delivered in 2 phases, both of which had different interventions (in both the intervention and control). While this is a promising finding, a larger study with greater participant numbers is needed to confirm the cost effectiveness of the intervention.

This study has important limitations to consider. Firstly, the ENTICE-CKD study was primarily designed to test the intervention's feasibility.[25] As such, the dietary outcomes were nominated as secondary outcomes and all clinical outcomes were exploratory to generate hypotheses for future studies. Secondly, reliable comparisons to usual care can only be drawn at 3 months, as our delayed contact control participants received an active intervention from 3 to 6 months. It is therefore unclear whether a longer-term lower intensity intervention, such as the non-tailored education-only text messages, may lead to similar results as observed in the tailored intervention over 6 months which could be more cost-effective. Thirdly, instead of using standard 24-hour ambulatory blood pressure, clinic blood pressure was measured as a

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pragmatic approach to align with routine clinical practice. Finally, the majority of participants reported following a healthy diet at baseline, as reflected in their high baseline diet quality score rating (above the median of 'high adherence' in population studies) and dietary sodium intake (in line with the suggested 100mmol/day), which raises the possibility of healthy volunteer bias and diminished potential for benefit from dietary intervention in a more representative cohort.

In conclusion, telehealth coaching appeared to have no effect on overall diet quality (as measured by the Alternative Healthy Eating Index) or clinic blood pressure at any time point, compared to usual care. Other exploratory markers of diet quality were improved, including the energy intake from the core food groups, number of servings of vegetables, dietary fiber and reduction of body weight at 3 months. All of these outcomes were exploratory, so there remains uncertainty in the findings which require further investigation. The findings from this study can be used to inform hypotheses for future telehealth coaching interventions to initiate and sustain improvements in dietary intake across the complexity of dietary recommendations for patients with CKD.

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Author contributions

JTK wrote the first draft of the manuscript and takes responsibility for the integrity of the data. JTK, KC, DJ, TH, DR, MR, JC, AT and SP assisted in the conceptualization of the trial design. JTK & MC designed the intervention materials and were responsible for the management of the trial at their respective sites. JK and RK provided recruitment logistic expertise and revised drafts of the manuscript. All authors contributed to revisions of the manuscript and approved the final version for submission.

Online Supplementary material

The online supplementary material contains four additional materials.

Supplemental Table 3. Page 7

Data sharing statement

The de-identified, individual participant data that underlie the results reported in this publication will be made available for sharing 24-months following article publication. The study protocol and statistical analysis plan can be requested by contacting the corresponding author. To request de-identified individual data, researchers will need to submit a proposal which will be assessed for appropriateness according to the following criteria: 1. methodologically sound proposal and data analysis plan; and 2. gained ethical clearance. Proposals may be submitted up to 24 months following article publication by contacting on request by contacting Bond University Research Data Management (research@bond.edu.au). Requesting researchers will need to sign a data access agreement before being approved to access the data for 12 months.

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Figure Legends

Figure 1: CONSORT diagram showing the flow of participants through the ENTICE-CKD study.

Table 1. Description of the ENTICE-CKD intervention according to the TIDieR checklist.[16]

Item Name/Number	Item Description
Item 1: Brief name	
ENTICE-CKD	
Item 2: Why	
Telehealth intervention may support patients with stage 3-4 CKD to improve their diet quality through access to education, coaching and regular contact with a health professional. Improving access to dietary education may assist people with stage 3-4 CKD reduce their dietary sodium intake <100mmol/day and improve their overall diet quality in line with the Australian Dietary Guidelines.[17] These dietary changes are complex and different levels of telehealth tailoring and intensity may be needed to support and sustain dietary behavior change.	
Item 3: What	
ENTICE-CKD program workbook (available on request)	
About ENTICE	Introduction page "The focus of the ENTICE program is to help you make gradual changes to your eating and physical activity habits that work for YOU – changes that become lifelong."
Section 1: Setting your goals and keeping track	"Use the following steps every time you set a SMART goal…"
Section 2: Eating well for healthy kidneys	"The ENTICE program will help you to gradually make changes to your diet to meet the daily recommended serves of fruit, vegetables and wholegrain breads/cereals."
Section 3: Active living	"Participating in regular physical activity and reducing sitting time is very important for your health and well-being."
Section 4: Why is healthy eating important for my kidneys?	Did you know? "Less than 4% of the Australians meet the recommended daily intake for vegetables. Research has shown that increasing your intake of vegetables by as little as ONE serve per day can help you live longer and stronger."
Section 5: Plan for success	"There are a number of things that affect what we eat and our overall energy intake. It is important to be aware of, pay attention to and plan for: How you eat; Where/why you eat?
Section 6: Self-monitoring and setting goals	Smart snacking Reflections Tracking my food intake
Section 7: Additional healthy eating resources	Useful websites; Healthy recipes Useful apps for mobiles or tablets High/low potassium/phosphate foods (if required) Healthier verse unhealthy takeaway options
Item 4: What – procedures	
Primary care physicians and treating nephrologists retained full responsibility over their patients' medical care at all times. The ENTICE-CKD intervention was adjunct to the usual care received, which in Australia, typically involves medical care with 3-monthly follow-up of patients with stage 4 CKD, and 3-6 monthly follow-up for patients with stage 3 CKD. Patients with stage 3-4 CKD do not typically receive dietary consultation with a dietitian, unless there is clinical indication.[48] **Prior to receiving allocated intervention:** Following a face-to-face baseline assessment with the local site investigator, all participants received the ENTICE-CKD workbook prior to receiving the randomized intervention, which was designed by dietitians specialized in kidney disease, with extensive academic, clinician and consumer input. **Phase 1:** Intensive coaching using telephone calls and tailored text messages. Each call was designed to align with each section of the workbook, and structured based on the 5As framework (Assess, Advise, Agree, Assist, Arrange).[49] The overall sequence of calls had the purpose of aligning participants' diets with a reduced dietary sodium intake to <100mmol/day and improving their overall diet quality in line with the Australian Dietary Guidelines.[17] **Intervention calls**	

Call 1

- Welcome to ENTICE-CKD
- Information about the program
- Feedback on baseline outcome measures
- Complete Section 1 – goal setting
- Discuss section 6 – self monitoring
- Begin section 2 - introduction the five food groups

Call 2

- Revisit goals
- Recap Australia Guide to Healthy Eating – answer any questions
- Continue section 2 – (plate model, snacks, salt, label reading, potassium and phosphate)

Call 3

- Revisit goals
- Answer any questions on healthy eating
- Complete section 3 – active living

Call 4

- Revisit goals
- Revisit any questions about active living/ healthy eating
- Complete section 4 – why is healthy eating important for my kidneys
- Complete section 5 - planning for success - how why and where you eat and managing slips

Call 5

- Revisit goals
- Answer any dietary or active living questions
- Discuss section 7 - additional information / resources

Call 6

- Revisit goals
- Revisit any questions participant may have
- Discuss where to from here
- Adjust text message frequency if desired

Text message component

Text message type	**SCT construct**	**Example text**	Intervention Phase 1	Intervention Phase 2	Control Phase 1	Control Phase 2
Education	Outcome expectations	Dietary fibre intake reduces ur cholesterol levels and controls ur blood sugar. Include wholegrain breads & cereals, fruits & veg regularly	2-6	1-4	NA[a]	6-8
Self-monitor	Self-regulation	Hi [name], are u keeping track of ur fruit/vegetable intake every day? Remember ur goal to have 5 serves this week	0-2	1-4	NA	NA
Goal check	Self-regulation	Hi [name], did u reach ur goal to eat 5 fruits/vegetables 4 times this week? Text me back yes or no to let me know	2	2-4	NA	NA
Education (Safety protocol)	Low potassium diet	Choose high fibre, low potassium breakfast cereals. Good choices are Multigrain Weetbix, Rolled Oats, Guardian, Oatbritz, Special K	0-2[a]	0-2[a]	NA	0-2 [a]

Phase 2: Extended contact using tailored text messages only.

At the end of phase 1 (3-month study mid-point), participants completed their final coaching call and discussed their preferences for the timing and frequency of the phase 2 text messages. At 18 weeks, participants received another tailoring call (no dietary coaching) to make individualized adjustments to their text message timing and frequency for the remaining 6 weeks of the intervention.

Item 5: Provider

Two accredited practicing dietitians (RD equivalent) with additional training in behavior change, motivational interviewing and kidney nutrition. Each participant in the intervention was assigned to one dietitian for the duration of the intervention.

Item 6: How

Phase 1 (month 0-3)	Intervention: One-to-one coaching provided through 6 phone calls every 2 weeks, and tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component).

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Phase 2 (month 3-6)	Intervention: Tailored text messages at a frequency requested by the participant (TIDieR item 4 – Text message component).
Item 7: Where	
Participants were in locations of their choosing as the intervention was delivered by telephone/mobile.	
Item 8: When and How Much	
Phone calls: Intervention group participants received phone calls every 2 weeks for 3 months Text messages: Intervention participants received text messages every 2 weeks for 6 months. Control group participants received text messages for 3 months (in phase 2 only) (TIDieR item 4 – Text message component).	
Item 9: Tailoring	
Phone calls: Coaches could tailor the dietary guidelines to participants' individual comorbidities and goals. Coaches documented any tailoring to the intervention in call logs. Text messages: Tailored text messages were tailored to participants' names, set goals and barriers to achieving each goal (examples can be seen under TIDieR item 4 – Text message component). Safety tailoring: where required, coaches tailored the food group suggestions to be electrolyte controlled, only when clinically indicated or directly requested by participants.	
Item 10: Modifications	
Some participants who replied to the goal check text messages in a way the system could not recognize (i.e. not a yes/no response) were giving a tailored goal check reply message instead of the automatic system generated reply. No other modifications were made to the intervention during the course of the study.	

Table 2: Baseline characteristics of participants in the ENTICE-CKD study. Data are reported as mean ± SD or Median (IQR).

Characteristic	Intervention n=41	Control n=39
Age, years	63 ± 12	61 ± 13
Gender, % male	63	64
Ethnicity, n (%)		
Asian	2 (5)	
Caucasian	35 (85)	1 (3)
European	2 (5)	29 (74)3 (8)
Indigenous	1 (2.5)	0 (0)
Other	1 (2.5)	6 (15)
Diabetes, n (%)	16 (39)	15 (39)
Cardiovascular disease, n (%)	14 (34)	12 (31)
Hypertension, n (%)	34 (83)	31 (80)
Anti-hypertensive medication, n (%)	38 (93)	34 (87)
Angiotensin-converting enzyme inhibitor	12	13
Angiotensin-receptor blocker	20	16
Alpha-blocker	9	1
Beta-blocker	20	18
Calcium channel blocker	15	15
Diuretic	19	17
Other	7	8
Total anti-hypertensive medication pill count at baseline, n	102	88
Serum potassium, mEq/L	4.6 ± 0.6	4.7 ± 0.5
Serum bicarbonate, mEq/L	26 ± 3	26 ± 3
Serum phosphate, mg/dL	3.7 ± 0.6	3.7 ± 0.6
Serum creatinine, mg/dL	2.0 ± 0.6	1.9 ± 0.7
eGFR, ml/min/1.73^2	36 ± 12	39 ± 12
Systolic blood pressure, mmHg	136 ± 18	131 ± 19
Diastolic blood pressure, mmHg	80 ± 12	78 ± 11
Weight, kg	96 ± 22	90 ± 19
BMI, kg/m^2	33 ± 7	31 ± 6
Waist circumference	113 ± 18	107 ± 18
Urine albuminuria, mg/L	120.0 (8.0, 442.0)	38.5 (13.0, 143.5)
Alternative Healthy Eating Index	71.4 (11.8)	69.6 (12.1)
Energy intake from the core food groups, %	62.8 ± 17.4	65.7 ± 13.9

Characteristic	Intervention n=41	Control n=39
Fruit, serves/day	1.5 ± 0.9	1.9 ± 1.5
Vegetables, serves/day	4.2 ± 2.0	5.4 ± 2.5*
Sodium, mg	2379.0 ± 1392.0	2260.0 ± 907.0
Fiber, g	24.1 ± 9.1	26.7 ± 9.6
Daily food costs, AUD[a]	12.8 ± 4.4	13.3 ± 3.7
Energy, kj	9472.0 ± 4837.0	9571.9± 2909.0
Energy, kj/kg	100.5 ± 55.3	111.4 ± 41.8
Protein, g	104.8 ± 51.3	111.3 ± 31.5
Protein, g/kg	1.1 ± 0.5	1.3 ± 0.5

Abbreviations: ACE: angiotensin converting enzyme, ARB: angiotensin receptor blocker, BMI: body mass index, CCB: calcium channel blocker, eGFR: estimated glomerular filtration rate, AUD: Australian Dollar.

[a] Daily food costs were calculated from each participants daily food intake using the Australian Eating Survey.

* p-value for between group difference at baseline <0.05

Table 3: Change from baseline in indices of diet quality and clinical assessment at 3 months and 6 months, adjusted for baseline values.

Variable	3 months			6 months		
	Intervention n=38	Control n=37	Mean Difference	Intervention n=38	Control n=37	Mean Difference
Diet quality index (secondary outcomes)						
Alternative Healthy Eating Index	4.3 (1.2, 7.5)*	2.1 (-1.7, 5.8)	3.2 (-1.3, 7.7)	3.4 (-0.3, 7.2)	3.8 (-0.1, 7.8)	0.5 (-4.6, 5.5)
Proportion of participants achieving a 5-point change in Alternative Healthy Eating Index, n (%)	19 (50.0)	14 (36.8)	φ= -0.13[a]	15 (39.5)	17 (44.7)	φ= -0.05[a]
Food groups (exploratory outcomes)						
Energy intake from the core food groups, %	10.3 (6.2, 14.4)***	3.3 (-1.2, 7.7)	5.8 (0.9, 10.7)*	11.3 (7.7, 14.8)***	4.2 (-0.1, 8.5)	5.4 (1.0, 9.8)*
Fruit, serves/day[b]	0.7 (0.3¸1.0)**	0.1 (-0.3, 0.6)	0.4 (-0.1, 0.9)	0.3 (0.0, 0.7)	0.2 (-0.3, 0.7)	0.0 (-0.6, 0.5)
Vegetables, serves/day[c]	1.3 (0.7, 1.9)***	-0.3 (-0.9, 0.2)	1.5 (0.6, 2.3)**	0.8 (0.2, 1.4)*	-0.1 (-0.8, 0.7)	0.3 (-0.6, 1.3)
Clinical measure						
Clinic blood pressure						
Systolic blood pressure, mmHg	-2 (-8, 5)	2 (-3, 8)	-1 (-8, 6)	-1 (-8, 7)	2 (-5, 8)	2 (-7, 10)

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Diastolic blood pressure, mmHg	-3 (-6, 1)	0 (-3, 4)	-2 (-6, 1)	-1 (-5, 3)	0 (-3, 3)	1 (-3, 4)
Serum blood chemistry						
Serum potassium, mEq/L[d]	-0.01 (-0.12, 0.10)	-0.01 (-0.15, 0.13)	-0.01 (-0.20, 0.20)	0.05 (-0.09, 0.20)	-0.04 (-0.18, 0.10)	0.08 (-0.10, 0.30)
Serum bicarbonate, mEq/L [d]	0.18 (-0.74, 1.11)	-0.03 (-0.94, 0.88)	0.07 (-1.10, 1.25)	0.32 (-0.51, 1.16)	1.79 (-2.34, 5.92)	-1.56 (-5.76, 2.66)
Serum phosphate, mEq/L[e]	-0.03 (-0.25, 0.19)	-0.09 (-0.04, 0.19)	0.00 (-0.34, 0.31)	0.12 (-0.12, 0.37)	-0.19 (-0.43, 0.06)	0.22 (-0.06, 0.37)
Exploratory outcomes						
Quality of life (measure name)						
Overall change in quality of life[f]	0.10 (0.03, 0.16)*	0.03 (-0.03, 0.09)	0.07 (-0.01, 0.15)	0.07 (0.01, 0.14)*	0.05 (-0.01, 0.12)	0.02 (-0.06, 0.10)

[a.] φ: Phi coefficient used to determine a relationship between two binary variables. A Phi <0.19 distinguishes a weak-to-negligible relationship.
[b.] Sample size at 3 months (n=37 for intervention; n=37 for control). Sample size at 6 months (n=34 for intervention; n=35 for control).
[c.] Sample size at 3 months (n=38 for intervention; n=36 for control). Sample size at 6 months (n=35 for intervention; n=36 for control).
[d.] Sample size at 3 months (n=38 for intervention; n=36 for control). Sample size at 6 months (n=37 for intervention; n=38 for control).
[e.] Sample size at 3 months (n=32 for intervention; n=35 for control). Sample size at 6 months (n=32 for intervention; n=37 for control).
[f.] Sample size at 3 months (n=36 for intervention; n=36 for control). Sample size at 6 months (n=37 for intervention; n=36 for control).
*P=<0.05; **P=<0.001; P=<0.0001